

Willmore F. Holbrow, III (SB# 169688)
bill_holbrow@bstz.com
James W. Ahn (SB#243335)
James_ahn@bstz.com
BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN, LLP
12400 Wilshire Boulevard, Seventh Floor
Los Angeles, California 90025
Tel: (310) 207-3800
Attorneys for Plaintiff
SAKURA FINETEK U.S.A., INC.

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION**

SAKURA FINETEK U.S.A., Inc., a
California corporation,

Plaintiff,

v.

SCI GEN, INC., d/b/a SCIGEN, California
corporation,

Defendant.

)
)
) **COMPLAINT FOR**
) **VIOLATIONS OF §43(A) OF**
) **THE LANHAM ACT, COMMON**
) **LAW TRADEMARK**
) **INFRINGEMENT AND**
) **STATUTORY UNFAIR**
) **COMPETITION**
)
)
) **[Demand For Jury Trial]**
)
)
)
)
)
)

1 Plaintiff SAKURA FINETEK U.S.A., INC. (“SAKURA”), for its complaint
2 against SCI GEN, INC. (“SCIGEN”), alleges as follows:
3

4 **JURISDICTION, VENUE AND PARTIES**

5 1. The Court has federal question jurisdiction of the Lanham Act claims
6 for false advertising and trade dress infringement pursuant to 28 U.S.C. §1331 and
7 supplemental jurisdiction of the related California state law claims for common law
8 trademark infringement and unfair competition pursuant to 28 U.S.C. §1367.

9 2. The Court has personal jurisdiction over the parties, as
10 Plaintiff Sakura has its headquarters in Torrance, and Defendant SCIGEN has a
11 presence and conducts business out of which the claims herein arise within
12 California and this District.

13 3. Venue is proper in this district under 28 U.S.C. §1391(a), in that the
14 Defendant is subject to personal jurisdiction in this District and under 28 U.S.C.
15 §1391(b) and (c) because a substantial part of the events giving rise to the claims
16 occurred in this District.

17 4. SAKURA is a California corporation, headquartered at 1750 West
18 214th St., Torrance, Los Angeles County, California.

19 5. SCI GEN, INC., doing business as SCIGEN, is a California corporation
20 located at 333 Gardena Blvd., Gardena, Los Angeles County, California.
21

22 **FACTS COMMON TO ALL CLAIMS**

23 6. At least as early as 1986, SAKURA has been an original manufacturer
24 and distributor of clinical pathology products sold in the United States and
25 worldwide. Since that time, its products have become the industry standard in
26 clinical pathology equipment and products, including histology, cryostat and
27 cytology, tissue processors, stainers, automated coverslippers, microtomes,
28

1 laboratory specimen embedding systems, laboratory fixatives, and laboratory safety
2 systems.

3 7. SAKURA's product line includes TISSUE-TEK®, CYTO-TEK® and
4 TISSUE-TEK VIP® products, which also includes the ACCU-EDGE BLADE
5 SYSTEMS®, TISSUE-TEK UNI-CASSETTE SYSTEMS®, TISSUE-TEK
6 PARAFORM®, TISSUE-TEK® CRYO3®, TISSUE-TEK XPRESS® x Series
7 Rapid Tissue Processors, TISSUE-TEK Auto TEC® Automated embedding
8 systems, and TISSUE-TEK® FORMAGO® Formalin Safety System, among others.
9 Its clinical pathology products have revolutionized the practice of clinical
10 pathology, as its innovations have dramatically reduced specimen processing
11 turnaround times, and have helped to standardize laboratory safety and processing
12 procedures in the field.

13 8. At least as early as December, 1994, SAKURA first introduced its
14 TISSUE-TEK® O.C.T. Compound to the U.S. market upon acquisition of such
15 assets and rights and has been using continuously since then.

16 9. TISSUE-TEK® O.C.T. Compound is an embedding medium for frozen
17 tissue specimens used to insure optimal cutting temperature ("O.C.T.") for such
18 specimens. It is used to bind tissue to a specimen block and to surround and cover
19 tissue specimens in preparation for sectioning before microscopic viewing.

20 10. SAKURA's container for its TISSUE-TEK® O.C.T. Compound
21 incorporates unique features which comprise its trade dress, including the term
22 TISSUE in large black font, a series of backslash markings circling the container,
23 and the words "O.C.T. Compound" underneath the backslashes, again in large black
24 font, followed by:
25
26
27
28

Embedding Medium for Frozen Tissue Specimens to ensure Optimal Cutting Temperature (O.C.T.)

For In Vitro Diagnostic Use

Poison: Not for drug, food or household use

118 ml

(4 Fl. Oz)

11. SAKURA's container for its TISSUE-TEK® O.C.T. Compound is a clear bottle with a black cap, and features Sakura's unique identifier "4583" mark, and incorporates the Hazardous Materials Identification System ("HMIS") grid. The features described above constitute SAKURA's Trade Dress in its TISSUE-TEK® O.C.T. Compound product (hereinafter, the "TRADE DRESS").

12. SAKURA originally began to use the numbers "4583" (hereinafter, the "MARK") on its TISSUE-TEK® O.C.T. Compound when the product was first introduced. "4583" is now recognized by the public to identify SAKURA as the source of TISSUE-TEK® O.C.T. Compound, as its customers identify the product by "4583" in the marketplace.

13. SAKURA has advertised and displayed its TISSUE-TEK® O.C.T. Compound extensively in commerce, since at least as early as 2002, including over the internet, by providing it to research physicians and laboratory scientists, and through various print media. It has expended considerable sums on its advertising and promotion of its product, and has generated a substantial amount of goodwill in the product and consumer awareness that SAKURA is the source of the product.

14. On August 1, 1997, SAKURA and Defendant SCIGEN entered into a supply agreement whereby SAKURA provided its specification and formulation to make the TISSUE-TEK® O.C.T. Compound to SCIGEN to enable SCIGEN to make the product for SAKURA. SAKURA gave notice of termination of the supply agreement on May 23, 2007. The termination became effective September 30, 2007. SAKURA conferred no rights of any kind to Defendant SCIGEN regarding

1 SAKURA's MARK or its trade dress either before termination of the supply
2 agreement, or post-termination.

3 15. In 2015, Defendant SCIGEN began to market a product to compete with
4 SAKURA's TISSUE-TEK® O.C.T. Compound, called SCIGEN TISSUE PLUS
5 O.C.T. Compound.

6 16. SCIGEN's product features the term TISSUE in large black font, a
7 series of backslash markings circling the container, the words "O.C.T. Compound"
8 underneath the backslashes, again in large black font, followed by the same terms
9 featured on SAKURA's product:

10 *Embedding Medium for Frozen Tissue Specimens to ensure Optimal Cutting*
11 *Temperature (O.C.T.)*

12 *For In Vitro Diagnostic Use*

13 *Poison: Not for drug, food or household use*

14 *118 ml*

15 *(4 Fl. Oz)*

16 17. SCIGEN's container for its TISSUE PLUS O.C.T. Compound also
17 incorporates a clear bottle with a black cap, features the "4583" Mark, and
18 incorporates the Hazardous Materials Identification System ("HMIS") grid.

19 18. SCIGEN's design choices for its TISSUE PLUS O.C.T. Compound are
20 identical to SAKURA's trade dress for its TISSUE-TEK® O.C.T. Compound, as
21 SCIGEN used the exact same clear container and black cap combination,
22 backslashes circling the container, the exact same text and color on its label, and the
23 identical placement of the HMIS grid on its product's label.

24 19. SCIGEN utilizes SAKURA's unique 4583 mark on its packaging, when
25 its inclusion of such number on its product label is unnecessary.

26 20. Defendant SCIGEN has offered and continues to offer its TISSUE
27 PLUS O.C.T. Compound for sale through the same channels to the same customers
28 and distributors as SAKURA, and on information and belief SCIGEN is erroneously

1 informing potential customers and distributors that the SCIGEN product is the same
2 as SAKURA's product.

3 21. Sakura has sold TISSUE-TEK® O.C.T. Compound extensively,
4 throughout the world, and, since before the offending activities of Defendant
5 complained herein, had developed a wide and favorable reputation under the MARK
6 and its TRADE DRESS.

7 22. Defendant SCIGEN's use in commerce of SAKURA's TRADE DRESS
8 in connection with its TISSUE PLUS O.C.T. Compound is likely to and has caused
9 confusion, deception and mistake in the minds of the public with respect to the
10 source and origin of SAKURA's products.

11 23. Defendant SCIGEN's use in commerce of SAKURA's MARK in
12 connection with its TISSUE PLUS O.C.T. Compound is likely to cause confusion,
13 deception and mistake in the minds of the public with respect to the source and
14 origin of SAKURA's products.

15 24. In February 2016, Sakura began marketing and selling its TISSUE-
16 TEK® FormaGO® Formalin Safety System. SAKURA's FormaGO® line of
17 products is used by laboratories to promote user safety and environmental safety in
18 the disposal of formalin. SAKURA's TISSUE-TEK® FormaGO® user safety
19 products include Absorption Pads, Absorption Wipes, and Absorption Granules; its
20 environmental safety products include the Formalin Neutralizer, Formaldehyde
21 Analysis Kit and Formalin Neutralizer Container.

22 25. SAKURA competes directly with SCIGEN in the formalin neutralizer
23 and related product market, through SCIGEN's manufacture, sales and marketing of
24 the SCIGEN NEUTRALEX products.

25 26. Formalin is primarily used in pathology laboratories for tissue fixation,
26 or as a preservative holding solution for fixed tissues or organ specimens. It is the
27 most common form of formaldehyde found in laboratories, and is typically made
28

1 from a mixture of 37-40% formaldehyde, water, and usually 10% methanol. This
2 mixture is commonly known as “Ten percent formalin”.

3 27. Due to potential health hazards associated with formaldehyde, the
4 disposal of formalin into the waste water system is subject to various federal, state
5 and local regulations. Improper disposal of formalin presents health and safety
6 concerns when handled incorrectly, and raises environmental concerns and risk of
7 legal liability when disposed incorrectly. A distinction is made in Federal
8 regulations between “used” and “unused” formalin when any disposal action is
9 planned.

10 28. “Used” Ten Percent formalin (i.e. the working solution) may be poured
11 down sink drains and then flushed through plumbing traps with significant amounts
12 of water. Disposal of used formalin to a sanitary sewer is permissible from a
13 regulatory perspective because the solution has been used for its intended purpose,
14 and at that stage, it is no longer considered a commercial chemical product such that
15 it would fall under the Federal Resource Conservation and Recovery Act (“RCRA”).
16 A spent solution does not contain the same constituents as the original unused
17 solution, as it has changed in nature from having been used, and as such, does not
18 meet the criteria stated in the RCRA regulations.

19 29. Used formalin working solution is not a hazardous waste because it is
20 not listed under the RCRA and it is not characteristic of hazardous waste.
21 Specifically, it does not have the RCRA characteristic of ignitability, corrosivity, or
22 toxicity, as required for designation as a hazardous waste.

23 30. Unused formalin and unused ten percent formalin solutions are both
24 considered commercial products, and fall within the regulations of the RCRA. Both
25 contain formaldehyde as the active ingredient. The regulations that implement the
26 RCRA identify unused formalin as a toxic waste, as identified by the U.S.
27 Environmental Protection Agency (“EPA”).
28

1 31. Federal regulations allow specified users under certain conditions to
2 treat their own spent formalin waste with products such as SAKURA's FormaGO®
3 product line, and several other commercially available formalin neutralizing
4 products, without obtaining a permit and without being regulated as a waste disposal
5 facility.

6 32. State and local regulations allow sewer disposal treated formalin waste
7 if local waste-water treatment plant ("WWTP") authorities and regulations are
8 satisfied. For example, California allows the treatment of hazardous wastes without
9 a permit generated in laboratories when relatively small quantities of hazardous
10 chemicals are used and the laboratory is associated with education, research,
11 chemical analysis, clinical testing, and product development.

12 33. The California Department of Toxic Substances Control categorizes
13 pathology laboratories as clinical testing facilities. Treatment of laboratory waste,
14 such as 10 percent formalin, may be disposed without a permit, as long as the
15 laboratory waste treatment methods have been published in either a peer-reviewed
16 scientific journal or the National Research Council's best practices publication.

17 34. On or about January 7, 2016, defendant SCIGEN began falsely
18 advertising that its NEUTRALEX formalin neutralizer product was sold pursuant an
19 exclusive right granted to it through certification issued through the California
20 Department of Toxic Substance Control ("DTSC"). A true and correct copy of its
21 advertisement is attached hereto as "Exhibit A".

22 35. SCIGEN's NEUTRALEX advertisement contains additional false
23 statements, namely, that "If [a product] is "Not Neutralex—you need a permit", "If
24 you are using any product other than NEUTRALEX, you must apply for a
25 Hazardous Waste Treatment Disposal Permit", "If it is not certified by the EPA –
26 You Must have a permit!" and "The EPA seal allows treatment of hazardous
27 formalin waste without having to obtain an EPA Hazardous Waste Treatment
28

1 Permit. Formalin treated by this certified process becomes a nonhazardous material
2 that can be legally poured down the drain.”

3 36. SCIGEN’s NEUTRALEX advertisements are false, misleading and
4 unsubstantiated.

5 37. The EPA does not issue federal certifications for formalin neutralizers.

6 38. California’s DTSC issued certifications under the California
7 Environmental Technology Certification Program. The certification process was
8 voluntary and all costs for testing certification were paid by the applicant.
9 Certification is not required independently for the safe disposal of formalin in
10 California or any other state. Additionally the DTSC makes no express or implied
11 warranties as to the performance of any manufacturer’s certified product, as the end
12 user is solely responsible for complying with the applicable federal, state and local
13 regulatory requirements. Due to a budget shortfall, the DTSC has stopped
14 accepting any new applications for DTSC certifications.

15 39. The DTSC certification does not give SCIGEN an exclusive right to
16 treat formaldehyde without a permit or advise potential customers that they can
17 dispose of the waste without a permit only if they use its NEUTRALEX product.
18 SCIGEN continues to advertise this to its consumers, although its statements are
19 false. There are several ten percent formalin neutralizers on the market, including
20 SAKURA’s, designed to effectively treat this type of waste.

21 40. SCIGEN intentionally continues to make unqualified claims about its
22 NEUTRALEX product in order to deceive consumers into purchasing its product
23 instead of competing products, such as SAKURA’s FORMAGO® product line.

24 41. SCIGEN’s false advertising campaign must be stopped to prevent
25 further consumer deception and irreparable harm to SAKURA.

26 42. SAKURA has and/or will suffer damages and Defendant SCIGEN has
27 made profits that are the proximate result of Defendant’s conduct complained of
28 herein. The amount of said damages and profits are presently unknown.

FIRST CLAIM FOR RELIEF
VIOLATION OF 15 U.S.C. §1125(a)(1) – False Advertising
(Section 43(a) of the Lanham Act)

43. Paragraphs 1 through 42 above are incorporated as though set forth at length.

44. Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. 1125(a)(1)(B), prohibits, *inter alia*, any “false or misleading description of fact, or false or misleading representation of fact which...in commercial advertising or promotion, misrepresents the nature, characteristics [or] qualities...of...goods, services, or commercial activities.”

45. SCIGEN’s advertising campaign for its NEUTRALEX product conveys a false message to consumers by grossly misstating the import of the certification issued to it by the DTSC, and necessarily implies that SCIGEN has an exclusive right to treat formaldehyde without a permit.

46. SCIGEN’s advertisement also conveys the false message that they can dispose of formaldehyde waste without a permit only if they use its NEUTRALEX product.

47. SCIGEN’s advertisement that “No Permit Needed” by purchase and use of its NEUTRALEX product is false and misleading because there may be some local or facility-specific regulations which require a permit for the disposal of formaldehyde products.

48. SCIGEN’s assertion that its DTSC certification is from the “EPA” is also false and misleading, as it implies that the California’s DTSC certification has national implications, when its value, if any, is limited to the state of California.

49. SCIGEN’s false and misleading claims have appeared in internet advertising, have been sent via email and have appeared in interstate commerce.

1 50. SCIGEN's false and misleading claims have deceived, and will continue
2 to deceive, a substantial portion of SAKURA's target audience for its FormaGO®
3 product line.

4 51. SCIGEN's false and misleading claims regarding its NEUTRALEX
5 product are material to consumers' purchasing decisions.

6 52. SCIGEN's misrepresentations has and likely will continue to cause
7 SAKURA to suffer damages to its business in the form of lost sales, profits, and
8 damage to its reputation and goodwill with its customers.

9 53. As a result of SCIGEN's intentional, deliberate and willful
10 misrepresentations, SAKURA and the public have been injured. Unless SCIGEN is
11 enjoined by this court and ordered to retract and correct its false and misleading
12 advertisements and statements, SCIGEN's statements will continue to mislead the
13 public and cause SAKURA to suffer a loss of consumer confidence, sales, profits,
14 and goodwill, along with the cost of remedial corrective advertising, much of which
15 loss is, and will be, irreparable. The exact nature and extent of SAKURA's injury
16 cannot be ascertained at this time.

17 **SECOND CLAIM FOR RELIEF**

18 (False Designation of Origin)

19 54. SAKURA hereby incorporates by reference the allegations contained in
20 paragraphs 1 through 53 as though fully set forth herein.

21 55. The SAKURA TRADE DRESS was originated by SAKURA, has been
22 exclusively used by SAKURA since at least as early as 2002 and is inherently
23 distinctive and non-functional.

24 56. By virtue of SAKURA's undisputed first use, advertising and
25 promotion of the SAKURA TRADE DRESS, the latter has established the presence
26 of secondary meaning identifiable with SAKURA's product.

27 57. Defendant, without the consent and authorization of SAKURA, has
28 adopted and utilized all the essential elements of the SAKURA TRADE DRESS.

1 58. Defendants' misappropriation of SAKURA's TRADE DRESS is likely
2 to cause purchasers in interstate commerce to be confused, misled and deceived
3 between SAKURA's TISSUE-TEK® O.C.T. Compound and SCIGEN's TISSUE
4 PLUS O.C.T. Compound.

5 59. Purchasers have also been given the false impression by Defendant that
6 the trade dress, style and presentation of SCIGEN's TISSUE PLUS O.C.T.
7 Compound was originally developed by Defendants and not SAKURA, and that its
8 product is the same as SAKURA'S product and/or associated with SAKURA's,
9 thereby diluting SAKURA's marketing advantage. The likelihood of confusion is
10 compounded by the fact that SCIGEN previously manufactured the product for
11 SAKURA and makes statements regarding same on its website.

12 60. Thus, the activities of Defendant alleged heretofore constitute the use in
13 commerce of false designations of origin and false description and representations
14 of fact as prescribed under §43(a) of the Lanham Act, and have damaged SAKURA
15 in an amount not yet subject to determination.

16 **THIRD CLAIM FOR RELIEF**

17 (False Designation of Origin)

18 61. SAKURA hereby incorporates by reference the allegations contained in
19 paragraphs 1 through 60 as though fully set forth herein.

20 62. The MARK was originated by SAKURA, has been exclusively used by
21 SAKURA and/or its predecessor in interest, since at least as early as 1994, and is
22 inherently distinctive and non-functional.

23 63. By virtue of SAKURA's undisputed first use, advertising and
24 promotion of the MARK, the latter has established the presence of secondary
25 meaning identifiable with SAKURA's product.

26 64. Defendant, without the consent and authorization of SAKURA, has
27 adopted and utilized the MARK.
28

1 65. Defendants' misappropriation of the MARK is likely to cause
2 purchasers in interstate commerce to be confused, misled and deceived about the
3 source of SCIGEN's TISSUE PLUS product and/or its connection or affiliation with
4 SAKURA.

5 66. Thus, the activities of Defendant alleged heretofore constitute the use in
6 commerce of false designations of origin and false description and representations
7 of fact as prescribed under §43(a) of the Lanham Act, and have damaged SAKURA
8 in an amount not yet subject to determination.

9 **FOURTH CLAIM FOR RELIEF**

10 (Common Law Trademark Infringement)

11 67. SAKURA hereby incorporates by reference the allegations contained in
12 paragraphs 1 through 66 as though fully set forth herein.

13 68. Defendants' conduct constitutes common law trademark infringement.

14 69. SAKURA is now suffering irreparable harm, and will continue to
15 suffer such harm if the infringing acts of Defendant are not enjoined, and it has no
16 adequate legal remedy for such injury.

17 70. Defendant's conduct is deliberate and willful.

18
19 **FIFTH CLAIM FOR RELIEF**

20 (Statutory Unfair Competition)

21 71. SAKURA incorporates by reference the allegations contained in
22 paragraphs 1 through 70 as though fully set forth herein.

23 72. Defendant's conduct constitutes unfair competition under Business &
24 Professions Code §17200, et seq. SAKURA is now suffering irreparable harm, and
25 will continue to suffer such harm if the infringing acts of Defendant are not
26 enjoined, and SAKURA has no adequate legal remedy for such injury.

27 73. Defendants' conduct is deliberate and willful.
28

PRAYER FOR RELIEF

WHEREFORE, SAKURA prays that this court enter judgment as follows:

1. That Defendant and its officers, agents, servants, employees and attorneys, and all persons acting in concert or participation with them or with any of the foregoing acts be enjoined permanently from:

a. Offering, soliciting, advertising, or selling any products or services under any mark, symbol, logo, or other indicia that include or consist of the MARK or any colorable imitation thereof;

b. Offering, soliciting, advertising, or selling any products under any mark, name, symbol, logo, trade dress or design which is likely to cause confusion or to cause mistake or to deceive persons into the erroneous belief that Defendant's products or services originate from SAKURA, or that Defendant or its products are authorized by SAKURA or are endorsed by SAKURA or are sponsored by SAKURA, or are connected in some way with SAKURA, SAKURA's MARK or SAKURA's TRADE DRESS;

c. Disseminating any advertising, marketing or promotional statements, whether made by expressly or by implication, that in any way says or suggests that "If [a product] is "Not NeutraleX—you need a permit", "If you are using any product other than NEUTRALEX, you must apply for a Hazardous Waste Treatment Disposal Permit", "If it is not certified by the EPA – You Must have a permit!", and "The EPA seal allows treatment of hazardous formalin waste without having to obtain an EPA Hazardous Waste Treatment Permit. Formalin treated by this certified process becomes a nonhazardous material that can be legally poured down the drain.";

d. Using false designations or engaging in any act or series of acts which, either alone or in combination, constitutes deceptive or unfair methods of competition with SAKURA and from otherwise interfering with, or injuring SAKURA's trademark or the goodwill associated therewith;

1 2. That Defendant be ordered to deliver to SAKURA for destruction, all
2 signs, advertisements, literature and any other promotional material which bears the
3 confusingly similar SCIGEN mark or any other mark confusingly similar to
4 SAKURA's MARK or TRADE DRESS;

5 3. That Defendant be ordered to immediately destroy all SAKURA's
6 products which feature trade dress characteristics confusingly similar to SAKURA's
7 MARK or TRADE DRESS;

8 4. That Defendant issue appropriate corrective advertising and literature;

9 5. That Defendant account for and pay to SAKURA, all gains, profits and
10 savings derived from their improper conduct;

11 6. That SAKURA recover its damages according to proof and that
12 Defendant account to SAKURA for all profits received by defendant from the
13 wrongful conduct pleaded herein, and that such damages and profits be trebled
14 under 15 U.S.C. §1117;

15 7. That SAKURA be awarded its costs, expenses and reasonable
16 attorneys' fees; and,

17 8. For such other relief as the court deems proper.
18

19 Dated: February 8, 2016

/s/Willmore F. Holbrow, III

Willmore F. Holbrow, III

James Ahn

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN, LLP

12400 Wilshire Boulevard, Suite 700

Los Angeles, California 90025

Attorneys for Plaintiff

SAKURA FINETEK U.S.A., INC.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury of all claims triable by jury.

Dated: February 8, 2016

/s/Willmore F. Holbrow, III

Willmore F. Holbrow, III

James Ahn

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN, LLP

12400 Wilshire Boulevard, Suite 700

Los Angeles, California 90025

Attorneys for Plaintiff

SAKURA FINETEK U.S.A., INC.